REMARKS

Claims 20-25, 27-29, 31-34, and 36-38 were pending in the present application. Claims 20-25 and 31-34 were considered allowable. Claims 27 and 36 have been cancelled, and claims 20 and 21 have been amended, without prejudice or disclaimer of any previously claimed subject matter. New claims 39-44 have been added. By virtue of this response, claims 20-25, 28-29, 31-34, and 37-44 are currently under consideration. A copy of the claims as amended is attached hereto as "Version with Markings to Show Changes Made".

Rejections under 35 U.S.C. §102(b)

The Office has rejected claims 27 and 29 as allegedly being anticipated by Berwing et al. (U.S. Patent No. 4,832,941). This rejection is traversed to the extent that it is applied to the amended claims.

Berwing et al. discloses microcapsules as a discrete phase in an aqueous vehicle. The microcapsules of Berwing et al. thus are not water-soluble. The microcapsules claimed include a water-soluble wall-forming material. The claimed microcapsules thus are water-soluble and would be able to dissolve in an aqueous vehicle. Berwing et al. does not identically disclose the claimed microcapsules which are formed of a water-soluble, wall-forming material, such as a protein. Berwing et al. relates to forming suspensions of gas bubbles in a liquid vehicle for echocardiography. Berwing et al. does not disclose the claimed compositions including microcapsules and a therapeutic agent. Berwing et al. does not identically disclose the claimed subject matter, as required for a proper rejection under 35 U.S.C. § 102(b). Therefore, withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §102(e)

The Office has rejected claim 27 as allegedly being anticipated by Erbel et al. (U.S. Patent No. 5,190,982). This rejection is traversed to the extent that it is applied to the amended claims.

Erbel et al. discloses ultrasonic contrast agents composed of microparticles that contain a gas and polyamino-dicarboxylic acid-co-imide derivatives that are suspended in water for use as ultrasonic contrast agents. Thus, Erbel et al. discloses microcapsules that do not dissolve in water and are not water-soluble. See, for example, col. 2, lines 5-20 of Erbel et al., which discloses that the microparticles are amenable to being suspended in water and form an inert matrix in which the gas is trapped. Erbel et al. does not identically disclose the compositions defined by the limitations of claim 20, which include microcapsules including a solid wall formed of a non-denatured, water-soluble wall-forming material. Moreover, Erbel et al. does not disclose microcapsules including a protein, peptide or enzyme wall forming material, as claimed. Applicant accordingly requests withdrawal of the rejection.

Rejections under 35 U.S.C. §112

The Office has rejected claims 27-29 and 36-38 under 35 U.S.C. § 112, first paragraph, and under 37 C.F.R. 1.75(c). The claims have been amended to promote prosecution, to obviate these rejections.

Accordingly, withdrawal of the rejection is requested.

Double Patenting Rejections

The Office has rejected claims 27-29 and 36-38 under the judicially created doctrine of obviousness-type double-patenting as being obvious over claims 1-6 of U.S. Pat. No. 5,518,709.

This rejection is traversed to the extent that it is applied to the amended claims. MPEP § 804 states that "[s]ince the doctrine of double patenting seeks to avoid unjustly extending patent rights at the expense of the public, the focus of any double patenting analysis necessarily is on the claims in the multiple patents or patent applications involved in the analysis." Double patenting involves a comparison of the multiple patents' claims. The claims, not the specification, define an invention, and it is the claims that are considered when assessing double

patenting. *Ortho Pharmaceutical Corp. v. Smith*, 959 F.2d 936, 22 USPQ2d 1119 (Fed. Cir. 1992).

The claims of U.S. Patent No. 5,518,709 are directed to a process of forming microcapsules for ultrasonic imaging having low solubility in water. In contrast, claims 20-25, 28-29, 31-34 and 37-38 are directed to a therapeutic composition for administration via the pulmonary airways, that includes microcapsules having a solid wall formed of a water-soluble wall-forming material, and a therapeutic agent that is optionally the wall forming material. The process claims of 5,518,709 do not suggest the therapeutic composition for administration via the pulmonary airways defined by the present claims.

Accordingly, Applicant requests that the double patenting rejection be withdrawn.

CONCLUSION

In view of the above arguments and amendments, it is submitted that the claims are in condition for allowance, and such action is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 263742002801.

Respectfully submitted,

Dated: December 18, 2002

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 27 and 36 have been cancelled.

Claims 20 and 21 have been amended as follows:

20. (Thrice Amended) A therapeutic ~~or diagnostic~~ composition for administration via the pulmonary airways comprising substantially dry, discrete microcapsules having a solid wall formed of a non-denatured, water-soluble wall-forming material, wherein the wall-forming material is ~~an amino or polyamino acid~~ a protein, peptide, or enzyme, and wherein said microcapsules have a mean size of between 1 and 10 μm, and a therapeutically effective amount of a therapeutic ~~or diagnostic~~ agent;

wherein the wall forming material optionally is the therapeutic ~~or diagnostic~~ agent.

21. (Amended) The composition according to claim 20, wherein said therapeutic ~~or diagnostic~~ agent is the sole component of the microcapsule.

Claims 39-44 are new.